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Respectfully submitted,

Dated: January 12, 2009

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

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In re Application of:	:	Examiner: P. Smith
	:	
Michael WHITMAN	:	
	:	
For: ELECTROMECHANICAL SURGICAL	:	
DEVICE	:	
	:	Art Unit: 3739
Filed: March 15, 2002	:	
	:	
Serial No.: 10/099,634	:	
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 P.O. Box 1450
 Alexandria, VA 22313-1450

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

SIR:

On June 12, 2008, Appellant filed a Notice of Appeal from the last decision of the Examiner contained in the Final Office Action dated December 12, 2007 in the above-identified patent application.

In accordance with 37 C.F.R. § 41.37, this brief is submitted in support of the appeal of the rejections of claims 1 to 9, 11 to 16, 19 to 21, and 37 to 51. For at least the reasons set forth below, the final rejections of claims 1 to 9, 11 to 16, 19 to 21, and 37 to 51 should be reversed.

1. REAL PARTY IN INTEREST

The real party in interest in the present appeal is POWER MEDICAL INTERVENTIONS, INC. of Langhorne, Pennsylvania, which is the assignee of the entire right, title and interest in and to the present application.

2. RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned, or believed by the undersigned to be known to

Appellant or the assignee, POWER MEDICAL INTERVENTIONS, INC., “which may be related to, directly affect or be directly affected by or have a bearing on the Board’s decision in the pending appeal.”

3. STATUS OF CLAIMS

Claims 10, 17, 18, and 22 to 36 have been canceled.

Claims 1 to 9, 11 to 16, 19 to 21, and 37 to 51 are pending.

Claims 1, 2, 7 to 9, 11, 12, 14 to 16, 19, 37 to 43, and 48 to 51 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of U.S. Patent No. 4,576,167 (“Noiles”) and U.S. Patent No. 5,402,769 (“Tsuji”).

Claims 3, 13, and 44 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Noiles, Tsuji, and U.S. Patent No. 6,099,464 (“Shimizu”).

Claims 4 to 6, 20, 21, and 45 to 47 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Noiles, Tsuji, and U.S. Patent No. 4,654,701 (“Yabe”).

A copy of the appealed claims, *i.e.*, claims 1 to 9, 11 to 16, 19 to 21, and 37 to 51, is attached hereto in the Claims Appendix.

4. STATUS OF AMENDMENTS

In response to the Final Office Action dated December 12, 2007, Appellant submitted a “Reply Under 37 C.F.R. § 1.116” on June 12, 2008. The Reply Under 37 C.F.R. § 1.116 did not include any proposed amendments to the claims. It is Appellant’s understanding that the claims as included in the annexed “Claims Appendix” reflect the current claims.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 relates to a flexible shaft. Claim 1 recites that the flexible shaft includes a flexible, elongated outer sheath. *Specification* at page 7, line 34 to page 8, line 1 and page 40, lines 11 to 14. Claim 1 recites that the flexible shaft includes at least one drive shaft disposed within the outer sheath. *Specification* at page 7, line 31 to page 8, line 14. Claim 1 recites that the flexible shaft includes a moisture sensor disposed within a coupling connected to an end of the outer sheath configured to communicate sensor data corresponding to the presence of moisture within the outer sheath. *Specification* at page 39, line 27 to page 40, line 4.

Independent claim 11 relates to a flexible shaft. Claim 11 recites that the flexible shaft includes a flexible, elongated outer sheath. *Specification* at page 7, line 34 to page 8, line 1 and page 40, lines 11 to 14. Claim 11 recites that the flexible shaft includes at least one flexible drive shaft disposed within the outer sheath. *Specification* at page 7, line 31 to page 8, line 14. Claim 11 recites that the flexible shaft includes a coupling connected to a distal end of the outer sheath configured to couple to a surgical attachment. *Specification* at page 34, lines 1 to 9. Claim 11 recites that the flexible shaft includes a moisture sensor disposed within the coupling configured to communicate sensor data corresponding to the presence of moisture. *Specification* at page 39, line 27 to page 40, line 4.

Independent claim 37 relates to a flexible shaft. Claim 37 recites that the flexible shaft includes a flexible, elongated outer sheath. *Specification* at page 7, line 34 to page 8, line 1 and page 40, lines 11 to 14. Claim 37 recites that the flexible shaft includes at least one drive shaft disposed within the outer sheath. *Specification* at page 7, line 31 to page 8, line 14. Claim 37 recites that the flexible shaft includes a coupling detachably connected to an end of the outer sheath, the coupling being configured to detachably couple to a surgical attachment. *Specification* at page 34, lines 1 to 9. Claim 37 recites that the coupling includes an engagement shaft including grooves and a clip having flanges, the flanges being received in longitudinal slits of a hollow engagement member of a surgical attachment, the engagement shaft being received in the clip, the clip engaging the grooves. *Specification* at page 39, lines 9 to 19. Claim 37 recites that the flexible shaft includes a moisture sensor disposed within the coupling configured to detect moisture within the outer sheath. *Specification* at page 39, line 27 to page 40, line 4.

Independent claim 38 relates to a flexible shaft. Claim 38 recites that the flexible shaft includes a flexible, elongated outer sheath. *Specification* at page 7, line 34 to page 8, line 1 and page 40, lines 11 to 14. Claim 38 recites that the flexible shaft includes at least one flexible drive shaft disposed within the outer sheath. *Specification* at page 7, line 31 to page 8, line 14. Claim 38 recites that the flexible shaft includes a coupling connected to a distal end of the outer sheath configured to couple to a surgical attachment. *Specification* at page 34, lines 1 to 9. Claim 38 recites that the coupling includes a connection mechanism configured to detachably couple to the surgical attachment, wherein the connection mechanism includes an engagement shaft having grooves and a clip having flanges, the clip being configured to be received in a hollow engagement member of a surgical attachment, the flanges of the clip configured to engage in longitudinal slits of the hollow engagement member, the clip configured to receive and secure the engagement shaft in the hollow

engagement member, and to frictionally engage with the grooves of the engagement shaft. *Specification* at page 38, line 33 to page 39, line 19. Claim 38 recites that the coupling further includes a moisture sensor. *Specification* at page 39, line 27 to page 40, line 4.

Independent claim 40 relates to a shaft. Claim 40 recites that the shaft includes an elongated outer sheath. *Specification* at page 7, line 34 to page 8, line 1 and page 40, lines 11 to 14. Claim 40 recites that the shaft includes at least one drive shaft disposed within the outer sheath. *Specification* at page 7, line 31 to page 8, line 14. Claim 40 recites that the shaft includes a moisture sensor disposed within a coupling connected to an end of the outer sheath configured to communicate sensor data corresponding to the presence of moisture within the outer sheath. *Specification* at page 39, line 27 to page 40, line 4.

6. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

- A. Whether claims 1, 2, 7 to 9, 11, 12, 14 to 16, 19, 37 to 43, and 48 to 51 are patentable under 35 U.S.C. § 103(a) over the combination of Noiles and Tsuji.
- B. Whether claims 3, 13, and 44 are patentable under 35 U.S.C. § 103(a) over the combination of Noiles, Tsuji, and Shimizu.
- C. Whether claims 4 to 6, 20, 21, and 45 to 47 are patentable under 35 U.S.C. § 103(a) over the combination of Noiles, Tsuji, and Yabe.

7. ARGUMENT

**A. Rejection of Claims 1, 2, 7 to 9, 11, 12, 14 to 16
19, 37 to 43, and 48 to 51 Under 35 U.S.C. § 103(a)**

i. Claims 1, 2, 7 to 9, 11, 12, 14 to 16, 19, 40 to 43, and 48 to 51

Claims 1, 2, 7 to 9, 11, 12, 14 to 16, 19, 40 to 43, and 48 to 51 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Noiles and Tsuji. It is respectfully submitted that the present rejection should be reversed for at least the following reasons.

Independent claim 1 relates to a flexible shaft. Claim 1 recites that the flexible shaft includes a flexible, elongated outer sheath. Claim 1 recites that the flexible shaft includes at least one drive shaft disposed within the outer sheath. Claim 1 recites that the flexible shaft includes a moisture sensor disposed within a coupling connected to an end of the outer sheath configured to communicate sensor data corresponding to the presence of moisture within the outer sheath.

Independent claim 11 relates to a flexible shaft. Claim 11 recites that the flexible shaft includes a flexible, elongated outer sheath. Claim 11 recites that the flexible

shaft includes at least one flexible drive shaft disposed within the outer sheath. Claim 11 recites that the flexible shaft includes a coupling connected to a distal end of the outer sheath configured to couple to a surgical attachment. Claim 11 recites that the flexible shaft includes a moisture sensor disposed within the coupling configured to communicate sensor data corresponding to the presence of moisture.

Independent claim 40 relates to a shaft. Claim 40 recites that the shaft includes an elongated outer sheath. Claim 40 recites that the shaft includes at least one drive shaft disposed within the outer sheath. Claim 40 recites that the shaft includes a moisture sensor disposed within a coupling connected to an end of the outer sheath configured to communicate sensor data corresponding to the presence of moisture within the outer sheath.

According to the Final Office Action, and as maintained in the Advisory Action, referring to Noiles, the threaded distal end portion 234, shoulder 235, rod 30, hollow extension tube 78, L-shaped slots 264, and retention ring 260 together comprise a coupling. Final Office Action, pages 2 to 3. The Final Office Action then asserts that “[a]t the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a moisture sensor such as that disclosed by Tsuji in the coupling disclosed by Noiles. A skilled artisan would be motivated to do so in order to enhance reusability by enabling sterilization, a necessary precondition of reusability in surgical instruments.” Final Office Action, page 3. Appellant disagrees.

Referring, for example, to Figures 3 and 5 of Noiles, it is readily apparent that there is no interior volume that is sealed from the external environment. For example, the space between extension tube 78 and the rod 30 is in communication with the external environment, as there is substantial clearance between the tube 78 and the rod 30 along the axial length. Moreover, the space between the outer tube shaft 60 and the extension tube 78 is in communication with space between the extension tube 78 and the rod 30 via the longitudinal slots 79, 279. As such, the space between the outer tube shaft 60 and the extension tube 78 is also in communication with the external environment. It is therefore clear that no portion within what the Final Office Action considers to be a coupling has any sealed interior portion. Accordingly, there is no apparent motivation or reason why one of ordinary skill in the art would include a moisture sensor within the portion of the Noiles device considered by the Examiner to constitute a coupling.

As regards the assertion at page 3 of the Final Office Action that one of skill in the art would be motivated to provide the moisture sensor of Tsuji in what the Examiner considers to be a coupling of Noiles “in order to enhance reusability by enabling sterilization,

a necessary precondition of reusability in surgical instruments,” there is no indication whatsoever that the presence of moisture within any portion of the device of Noiles, which does not include any internal electronics, would make the device any less sterilizable. Indeed, the presence of moisture within the components considered by the Examiner to constitute a coupling is irrelevant to the sterilizability, as any internal volumes and surfaces of these components are plainly exposed to the outer environment, *e.g.*, the surgical site, and would therefore require sterilization regardless of the presence of moisture.

As indicated above, it is plainly apparent that the combination of Noiles and Tsuji does not disclose, or even suggest, a coupling connected to a distal end of an outer sheath and a moisture sensor disposed within the coupling, as recited in the present claims.

As best understood, the Final Office Action appears to rely on a teaching, suggestion, or motivation to combine references to modify or combine the references to arrive at the claimed features. *See, e.g.*, Final Office Action, page 3, para. [07c] (“A skilled artisan would be motivated . . .”). However, M.P.E.P. § 2143 states that

Office personnel ***must*** articulate the following:

(1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;

(2) a finding that there was reasonable expectation of success; and

(3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

(Emphasis added). As set forth above, there is no apparent motivation for one of ordinary skill in the art to combine the references in the manner suggested by the Final Office Action. Further, the present rejection is deficient for at least the additional reason that it does not articulate a finding of a reasonable expectation of success.

Further regarding claims 1 and 40, the Examiner has not shown how, even if the references are combined as suggested, the sensor of Tsuji would be configured to communicate sensor data corresponding to the presence of moisture within an outer sheath of Noiles to which the components considered by the Examiner to constitute a coupling are attached. Thus, the Examiner has not established how the proposed combination would be “configured to communicate sensor data corresponding to the presence of moisture within the outer sheath” as recited in claims 1 and 40. Accordingly, the Examiner has not established a *prima facie* case of obviousness for claims 1 and 40 for at least this additional reason.

In view of all of the foregoing, it is plainly apparent that the Final Office Action and the Advisory Action have not properly established a prima facie case of obviousness as required under *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 U.S.P.Q.2d 1385 (2007) or in compliance with M.P.E.P. § 2141 et seq. with regard to any of claims 1, 11, and 40, or any of dependent claims 2, 7 to 9, 12, 14 to 16, and 19, 41 to 43, and 48 to 51.

It is further noted that the Examiner's comments in the Advisory Action do not appear relevant to the present rejection's critical deficiencies as set forth in the Reply Under 37 C.F.R. § 1.116 and herein, *e.g.*, the failure to establish a rationale for the proposed combination as required under *KSR*.

In view of all of the foregoing, reversal of the present rejection is respectfully requested.

ii. **Claims 37 to 39**

Claims 37 to 39 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Noiles and Tsuji. It is respectfully submitted that the present rejection should be reversed for at least the following reasons.

Independent claim 37 relates to a flexible shaft and recites, *inter alia*, a coupling detachably connected to an end of the outer sheath and a moisture sensor disposed within the coupling configured to detect moisture within the outer sheath.

Independent claim 38 relates to a flexible shaft and recites, *inter alia*, a coupling connected to a distal end of the outer sheath wherein the coupling includes a moisture sensor.

As indicated above, the combination of Noiles and Tsuji does not disclose, or even suggest, a coupling connected to a distal end of an outer sheath and a moisture sensor disposed within the coupling. For at least the same reasons set forth above with respect to the rejection of claims 1, 2, 7 to 9, 11, 12, 14 to 16, and 19, 40 to 43, and 48 to 51, it is respectfully submitted that the combination of Noiles and Tsuji does not render unpatentable either of claims 37 and 38.

Claim 39 depends from claim 38 and therefore includes all of the features recited in claim 38. As such it is respectfully submitted that the combination of Noiles and Tsuji does not render unpatentable claim 38. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988) (any dependent claim that depends from a non-obvious independent claim is non-obvious).

In view of all of the foregoing, reversal of this rejection is respectfully requested.

B. Rejection of Claims 3, 13, and 44 Under 35 U.S.C. § 103(a)

Claims 3, 13, and 44 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Noiles, Tsuji, and Shimizu. It is respectfully submitted that the present rejection should be reversed for at least the following reasons.

Claim 3 depends from claim 1, claim 13 depends from claim 11, and claim 44 depends from claim 40. As indicated above, the combination of Noiles and Tsuji does not render unpatentable any of claims 1, 11, and 40. Shimizu does not cure the critical deficiencies of the combination of Noiles and Tsuji. As such, it is respectfully submitted that the combination of Noiles, Tsuji, and Shimizu does not render unpatentable: claim 3, which depends from claim 1; claim 13, which depends from claim 11; or claim 44, which depends from claim 40. *Id.*

C. Rejection of Claims 4 to 6, 20, 21, and 45 to 47 Under 35 U.S.C. § 103(a)

Claims 4 to 6, 20, 21, and 45 to 47 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Noiles, Tsuji, and Yabe. It is respectfully submitted that the present rejection should be reversed for at least the following reasons.

Claims 4 to 6 depend from claim 1, claims 20 and 21 depend from claim 11, and claims 45 to 47 depend from claim 40. As indicated above, the combination of Noiles and Tsuji does not render unpatentable any of claims 1, 11, and 40. Yabe does not cure the critical deficiencies of the combination of Noiles and Tsuji. As such, it is respectfully submitted that the combination of Noiles, Tsuji, and Yabe does not render unpatentable: claims 4 to 6, which depend from claim 1; claims 20 and 21, which depend from claim 11; or claims 45 to 47, which depend from claim 40. *Id.*

In view of all of the foregoing, reversal of this rejection is respectfully requested.

8. CLAIMS APPENDIX

A “Claims Appendix” is attached hereto and appears on the four (4) pages numbered “Claims Appendix 1” to “Claims Appendix 4.”

9. EVIDENCE APPENDIX

No evidence has been submitted pursuant to 37 C.F.R. §§ 1.130, 1.131 or 1.132. No other evidence has been entered by the Examiner or relied upon by Appellant in the appeal. An “Evidence Appendix” is nevertheless attached hereto and appears on the one (1) page numbered “Evidence Appendix.”

10. RELATED PROCEEDINGS APPENDIX

As indicated above in Section 2, above, “[t]here are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned, or believed by the undersigned to be known to Appellant or the assignee, POWER MEDICAL INTERVENTIONS, INC., ‘which may be related to, directly affect or be directly affected by or have a bearing on the Board’s decision in the pending appeal.’” As such, there no “decisions rendered by a court or the Board in any proceeding identified pursuant to [37 C.F.R. § 41.37(c)(1)(ii)]” to be submitted. A “Related Proceedings Appendix” is nevertheless attached hereto and appears on the one (1) page numbered “Related Proceedings Appendix.”

11. CONCLUSION

For at least the reasons indicated above, Appellant respectfully submits that the art of record does not disclose or suggest the subject matter as recited in the claims of the above-identified application. Accordingly, it is respectfully submitted that the subject matter as set forth in the claims of the present application is patentable.

In view of all of the foregoing, reversal of all of the rejections set forth in the Final Office Action is therefore respectfully requested.

Respectfully submitted,

Dated: January 12, 2009

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CLAIMS APPENDIX

1. A flexible shaft, comprising:
 - a flexible, elongated outer sheath;
 - at least one drive shaft disposed within the outer sheath; and
 - a moisture sensor disposed within a coupling connected to an end of the outer sheath configured to communicate sensor data corresponding to the presence of moisture within the outer sheath.
2. The flexible shaft according to claim 1, wherein the outer sheath is autoclavable.
3. The flexible shaft according to claim 2, wherein the outer sheath includes a fluoropolymer/silicone material.
4. The flexible shaft according to claim 1, further comprising:
 - a memory unit disposed in the coupling.
5. The flexible shaft according to claim 4, wherein the memory unit stores data including at least one of serial number data, identification data and usage data.
6. The flexible shaft according to claim 5, further comprising:
 - a data transfer cable disposed within the outer sheath, wherein the memory unit is logically and electrically connected to the data transfer cable.
7. The flexible shaft according to claim 1, wherein the coupling is configured to detachably couple to a surgical attachment.
8. The flexible shaft according to claim 7, wherein the detachable coupling includes a locking mechanism for detachably coupling to the outer sheath.
9. The flexible shaft according to claim 8, wherein the locking mechanism includes a flexible strip locking mechanism.
11. A flexible shaft, comprising:
 - a flexible, elongated outer sheath;

at least one flexible drive shaft disposed within the outer sheath;
a coupling connected to a distal end of the outer sheath configured to couple to a surgical attachment; and
a moisture sensor disposed within the coupling configured to communicate sensor data corresponding to the presence of moisture.

12. The flexible shaft according to claim 11, wherein the outer sheath is autoclavable.

13. The flexible shaft according to claim 12, wherein the outer sheath includes a fluoropolymer/silicone material.

14. The flexible shaft according to claim 11, wherein the coupling includes a locking mechanism so that the coupling attaches and detaches to the outer sheath.

15. The flexible shaft according to claim 14, wherein the locking mechanism includes a flexible strip locking mechanism.

16. The flexible shaft according to claim 11, wherein the coupling includes a connection mechanism configured to detachably couple to the surgical attachment.

19. The flexible shaft according to claim 11, wherein the moisture sensor is configured to detect moisture in one of the coupling and the outer sheath.

20. The flexible shaft according to claim 11, further comprising:
a memory unit disposed within one of the outer sheath and the coupling, the memory unit configured to store data.

21. The flexible shaft according to claim 19, wherein the memory unit stores data including at least one of serial number data, identification data and usage data.

37. A flexible shaft, comprising:
a flexible, elongated outer sheath;
at least one drive shaft disposed within the outer sheath;

a coupling detachably connected to an end of the outer sheath, the coupling being configured to detachably couple to a surgical attachment, wherein the coupling includes an engagement shaft including grooves and a clip having flanges, the flanges being received in longitudinal slits of a hollow engagement member of a surgical attachment, the engagement shaft being received in the clip, the clip engaging the grooves; and

a moisture sensor disposed within the coupling configured to detect moisture within the outer sheath.

38. A flexible shaft, comprising:

a flexible, elongated outer sheath;

at least one flexible drive shaft disposed within the outer sheath; and

a coupling connected to a distal end of the outer sheath configured to couple to a surgical attachment, wherein the coupling includes a connection mechanism configured to detachably couple to the surgical attachment, wherein the connection mechanism includes an engagement shaft having grooves and a clip having flanges, the clip being configured to be received in a hollow engagement member of a surgical attachment, the flanges of the clip configured to engage in longitudinal slits of the hollow engagement member, the clip configured to receive and secure the engagement shaft in the hollow engagement member, and to frictionally engage with the grooves of the engagement shaft;

wherein the coupling further includes a moisture sensor.

39. The flexible shaft according to claim 38, wherein the connection mechanism includes a hollow engagement member having longitudinal slits and a clip having flanges, the clip being disposed in the hollow engagement member, flanges of the clip engaging in the longitudinal slits, the clip configured to receive and secure an engagement shaft of a surgical attachment.

40. A shaft, comprising:

an elongated outer sheath;

at least one drive shaft disposed within the outer sheath; and

a moisture sensor disposed within a coupling connected to an end of the outer sheath configured to communicate sensor data corresponding to the presence of moisture within the outer sheath.

41. The shaft according to claim 40, wherein the shaft is rigid.
42. The shaft according to claim 40, wherein the shaft is at least one of articulable and articulatable.
43. The shaft according to claim 40, wherein the outer sheath is autoclavable.
44. The shaft according to claim 40, wherein the outer sheath includes a fluoropolymer/silicone material.
45. The shaft according to claim 40, further comprising:
a memory unit disposed in the coupling.
46. The shaft according to claim 45, wherein the memory unit stores data including at least one of serial number data, identification data and usage data.
47. The shaft according to claim 45, further comprising:
a data transfer cable disposed within the outer sheath, wherein the memory unit is logically and electrically connected to the data transfer cable.
48. The shaft according to claim 40,
wherein the coupling is configured to detachably couple to a surgical attachment.
49. The shaft according to claim 48, wherein the detachable coupling includes a locking mechanism for detachably coupling to the outer sheath.
50. The flexible shaft according to claim 1, wherein the moisture sensor communicates the sensor data via a data transfer cable.
51. The flexible shaft according to claim 1, wherein the moisture sensor comprises a board element, a first lead, and a second lead, the first lead and the second lead printed on the board element, the electrical resistance between the first lead and the second lead varying in accordance with an amount of moisture present.

EVIDENCE APPENDIX

No evidence has been submitted pursuant to 37 C.F.R. §§1.130, 1.131, or 1.132. No other evidence has been entered by the Examiner or relied upon by Appellant in the appeal.

RELATED PROCEEDINGS APPENDIX

As indicated above in Section 2 of this Appeal Brief, “[t]here are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned, or believed by the undersigned to be known to Appellant or the assignee, POWER MEDICAL INTERVENTIONS, INC., ‘which may be related to, directly affect or be directly affected by or have a bearing on the Board’s decision in the pending appeal.’” As such, there no “decisions rendered by a court or the Board in any proceeding identified pursuant to [37 C.F.R. § 41.37(c)(1)(ii)]” to be submitted.